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DECLARATION

I, Natsuko Tosa, hereby declare:

that I am a translator belonging to KYOWEY INT'L of 2-32-1301 Tamatsukuri-Motomachi, Tennoji-ku, Osaka, 543-0014 Japan;

that I am well acquainted with both the Japanese and English languages;

that the attached document is a true translation of Japanese Patent Application No. 2002-193844 to the best of my knowledge and belief.

I also declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statements is directed.

Dated February 20, 2008

A handwritten signature in black ink, appearing to be "Natsuko Tosa".

Signature

Natsuko Tosa



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【Inventor】	
【Address】	c/o ARKRAY, Inc. 57, Nishiaketa-cho, Higashikujo, Minami-ku, Kyoto-shi, Kyoto Japan
【Name】	Tetsuya Sakata
【Applicant】	
【Identification Number】	000141897
【Address】	57, Nishiaketa-cho, Higashikujo, Minami-ku, Kyoto-shi, Kyoto Japan
【Name】	ARKRAY, Inc.
【Attorney】	
【Identification Number】	100086380
【Patent Attorney】	
【Name】	Minoru Yoshida
【Telephone Number】	06-6764-6664

【Attorney】

【Identification Number】 100103078

【Patent Attorney】

【Name】 Tatsuya Tanaka

【Attorney】

【Identification Number】 100105832

【Patent Attorney】

【Name】 Yoshikazu Fukumoto

【Attorney】

【Identification Number】 100117167

【Patent Attorney】

【Name】 Takashi Shiotani

【Attorney】

【Identification Number】 100117178

【Patent Attorney】

【Name】 Hiroshi Furusawa

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【Title of the Invention】 LANCING UNIT AND LANCING APPARATUS

【Claims】

【Claim 1】

A lancing unit comprising a lancing member, an auxiliary part, and a supporter supporting each of the lancing member and the auxiliary part, wherein the lancing member and the auxiliary part are detachably supported by the supporter.

【Claim 2】

The lancing unit according to claim 1, further comprises a cap for covering a needle of the lancing member, the cap being detachable from the lancing member, wherein the cap is attached to or integrally formed on the supporter, so that the lancing member is supported by the supporter via the cap.

【Claim 3】

The lancing unit according to claim 2, wherein the supporter comprises a case, and wherein the case accommodates the lancing member, the cap, and the auxiliary part.

【Claim 4】

The lancing unit according to claim 3, further comprises a lid for closing the open end of the case.

【Claim 5】

The lancing unit according to any one of claims 2-4, wherein the lancing member includes a body holding the needle,

wherein the cap is integrally formed on the body, and wherein a boundary portion between the cap and the body has a structure which causes a stress to be concentrated on the boundary portion more than on other portions of the cap and the body.

【Claim 6】

The lancing unit according to any one of claims 2-5, wherein a direction in which the auxiliary part is detachable from the supporter corresponds to a direction in which the cap is detachable from the lancing member.

【Claim 7】

The lancing unit according to any one of claims 2-6, wherein the cap is formed separately from the supporter and bonded to the supporter, and wherein the auxiliary part is detachably supported by the cap.

【Claim 8】

The lancing unit according to claim 7, wherein the supporter includes a convex or concave portion for fitting to a part of the cap to hold the cap in a standing posture, wherein the auxiliary part includes a portion for detachably supporting the cap.

【Claim 9】

A lancing apparatus for performing lancing by utilizing the lancing unit according to any one of claims 1-8, comprising:

a first holder brought into contact with the lancing member of the lancing unit when the lancing unit is set, for holding the lancing member of the lancing unit;
a moving mechanism for advancing the first holder when a predetermined operation is performed; and
a second holder for holding the auxiliary part when the lancing member is held by the first holder.

【Detailed Description of the Invention】

【0001】

【Field of the Invention】

The present invention relates to a lancing apparatus used to extract body fluid such as blood. It also relates to a lancing unit holding a disposable part as a unit and used as mounted to such a lancing apparatus.

【0002】

【Prior Art】

For diabetes treatment, management of the blood glucose level by a patient himself or herself is important for maintaining the blood glucose level in a normal range. Particularly, for a patient of insulin-dependent diabetes, regular measurement of the blood glucose level is essential to maintain the blood glucose level in a normal range. However, it is troublesome to often

go to a medical institution for measuring the blood glucose level. Conventionally, therefore, apparatuses which enable the extraction and analysis of blood without going to a medical institution have been proposed. For example, JP-A 2001-74731 discloses a lancing unit and a lancing apparatus as shown in Figs. 17(a), (b).

【0003】

The lancing unit 9 shown in Fig. 17(a) includes a lancet 90 as a lancing member, and a first housing 91A accommodating part of the lancet. The first housing 91A is fixedly fitted to a second housing 91B. As shown in Fig. 17(b), the second housing 91B is provided with a test strip 92. The first housing 91A has an opening 91a which is closed by a cover 93 so that a sterilized needle 90a of the lancet 90 can be kept hygienically clean. The first and the second housings 91A and 91B are wrapped by a wrapping member 94 in the form of a bag or case.

【0004】

The lancing unit 9 having the above-described structure is assembled by setting the needle 90a of the lancet 90 into the first housing 91A after the needle 90a is sterilized and then fixing the first housing 91A to the second housing 91B. With such an assembling method, the sterilization of the lancet 90 can be performed independently without adversely affecting the test piece 92. For example, unlike the above, when the

sterilization of the lancet 90 is performed after the lancing unit 9 is completely assembled, a constituent of the test piece 92 may be unduly changed due to the sterilization process. With the above assembling method, however, such a problem can be avoided.

【0005】

As shown in Fig. 17(b), the lancing apparatus 8 includes a housing case 80. The first and the second housings 91A and 91B can be mounted to the apparatus when they are pushed to a front end 80a of the housing case 80. Therefore, the lancet 90 and the test piece 92 can be mounted simultaneously. When the lancet 90 pushes a lancet holder 81 to the right in the figure, a spring 82 is compressed to bring the lancing apparatus 8 into a locked state. Thereafter, when an operation switch 83 is operated with the lancing apparatus 8 pressed against the skin of a human body, the lancet holder 81 and the lancet 90 advance to the left in the figure due to the resilient force of the spring 82, whereby the needle 90a of the lancet 90 lances the skin of the human body. The blood bleeding from the skin as a result of the lancing is introduced to the test sheet 92 through the blood introducing portion 95. The blood can be analyzed by optically detecting the color reaction of the test piece 92.

【0006】

【Problems to be Solved】

However, in the prior art arrangement, to mount the lancet 90 and the test piece 92 to the lancing apparatus 8, both of the first and the second housings 91A and 91B of the lancing unit 9 need be mounted to the lancing apparatus 8. Therefore, the front end of the lancing apparatus 8 needs to be made relatively large. As a result, the size of the lancing apparatus 8 increases, which is inconvenient for carrying.

【0007】

Further, the prior art arrangement has the following problem. From a hygienic point of view, the needle 90a of the lancet 90 need be hermetically sealed in the first housing 91A of the lancing unit 9. For this purpose, the portion where the first housing 91A and the lancet 90 are fitted together need be hermetically sealed. On the other hand, after the first housing 91A along with the lancet 90 is mounted to the lancing apparatus 8 and the lancet holder 81 is advanced, the lancet 90 needs to move smoothly relative to the first housing 91A in accordance with the movement of the lancet holder. However, to hold the lancet 90 in the first housing 91A in such a manner as to satisfy the above two requirements is not easy. Thus, the needle 90a of the lancet 90 sometimes is not hermetically sealed, or the lancet 90 after it is mounted to the lancing apparatus 8 sometimes does not move smoothly.

【0008】

Still further, since the lancing unit 9 requires the first housing 91A and the cover 93 for sealing a part of the lancet 90, the number of parts of the lancing unit 9 is large, whereby the manufacturing cost is relatively high. When mounting the lancet 90 to the lancing apparatus 8, it is necessary to remove the cover 93 from the first housing 91A, which may be troublesome.

【0009】

The present invention has been proposed under the above-described circumstances. It is therefore an object of the present invention to provide a usable lancing unit capable of preventing increasing the size of the lancing apparatus. Another object of the present invention is to provide a lancing apparatus suitable for using such lancing unit.

【0010】

【Means for Solving the Problems】

To solve the above problems, the present invention provides the following technical means.

【0011】

According to a first aspect of the present invention, there is provided a lancing unit comprising a lancing member, an auxiliary part which is separate from the lancing member, and a supporter detachably supporting each of the lancing member and the auxiliary part, wherein the lancing member and the auxiliary part are detachably supported by the supporter. The lancing

member and the auxiliary part are not limited to be directly supported by the supporter, but may be indirectly supported by the supporter.

【0012】

With such structure, mounting of the lancing member and the auxiliary part to the lancing apparatus is performed with the lancing member and the auxiliary part supported by the supporter, and then the supporter is detached from the lancing member and the auxiliary part. Thus, there is no need to design the lancing apparatus to have a dimension for mounting the supporter thereto, and it is possible to reduce the size of the lancing apparatus.

【0013】

Preferably, the lancing unit further comprises a cap for covering a needle of the lancing member, the cap being detachable from the lancing member. The cap is attached to or integrally formed on the supporter, so that the lancing member is supported by the supporter via the cap. With such structure, the cap for covering the needle of the lancing member is detachable from the lancing member together with the supporter. Thus, the detaching of the cap from the lancing member is facilitated, which is convenient. Since the lancing member can be mounted to the lancing apparatus by itself, differently from the conventional lancing member, there is no need to slidably support the lancing member by a predetermined member (first housing 91A) of the

lancing unit. As a result, the structure of the lancing unit is simplified, and proper operation of the lancing member is secured when mounting the lancing member to the lancing apparatus. When the lancing unit is not in use, the needle of the lancing member is covered by the cap which, differently from the conventional one, does not need a plurality of members. Thus, the number of parts of the lancing unit is reduced, and the structure of the lancing unit is simplified as described above, so that the product cost of the lancing unit is reduced.

【0014】

Preferably, the supporter comprises a case, and the case accommodates the lancing member, the cap, and the auxiliary part. With such structure, in keeping the lancing unit before use, the lancing member, the cap, and the auxiliary part are protected by the case. When the supporter includes a tubular (not limited to cylindrical) case, the tubular case is slidably mounted to a proper portion of the lancing apparatus, so that the lancing member and the auxiliary part are properly guided to predetermined positions of the lancing apparatus.

【0015】

Preferably, the lancing unit further comprises a lid for closing the open end of the case. With such structure, the case is sealed to prevent the quality of the auxiliary part from being deteriorated.

【0016】

Preferably, the lancing member includes a body holding the needle, and the cap is integrally formed on the body. A boundary portion between the cap and the body has a structure which causes a stress to be concentrated on the boundary portion more than on other portions of the cap and the body. For causing the stress concentration, the boundary portion may be a constricted configuration, or may be formed with perforations without exposing the needle of the lancing member. With such structure, since the cover is integrally formed with the body, its manufacture is facilitated and thus the product cost is reduced. Further, detachment of the cap and the lancing member is easily and reliably performed by breaking the boundary portion.

【0017】

Preferably, a direction in which the auxiliary part is detachable from the supporter corresponds to a direction in which the cap is detachable from the lancing member. With such structure, when detaching the lancing member from the supporter after mounting the lancing member and the auxiliary part to the lancing apparatus, the auxiliary part is also detached from the supporter. Thus, the operation for mounting the lancing member and the auxiliary part to the lancing apparatus is further facilitated.

【0018】

Preferably, the cap is formed separately from the supporter and bonded to the supporter, while the auxiliary part is detachably supported by the cap. With such structure, the mounting of the cap and the auxiliary part to the supporter is simplified, and thus the product cost is further reduced. Further, in the assembly step in which the auxiliary part is supported by the supporter, the above-described members other than the auxiliary part may be properly subjected to sterilization by e.g. γ -ray irradiation.

【0019】

Preferably, the supporter includes a convex or concave portion for fitting to a part of the cap to hold the cap in a standing posture. The auxiliary part includes a portion for detachably supporting the cap. With such structure, the assembly of the cap and the auxiliary part is facilitated.

【0020】

According to a second aspect of the present invention, there is provided a lancing apparatus for performing lancing by utilizing the lancing unit according to any one of claims 1-8, comprising: a first holder brought into contact with the lancing member of the lancing unit when the lancing unit is set, for holding the lancing member of the lancing unit; a moving mechanism for advancing the first holder when a predetermined operation is performed; and a second holder for holding

the auxiliary part when the lancing member is held by the first holder.

【0021】

With such structure, the lancing member and the auxiliary part of the lancing unit according to the first aspect of the present invention are properly mounted to the lancing apparatus, and lancing operation using those members is properly performed.

【0022】

Other features and advantages of the present invention will be apparent from the following description of the embodiments.

【0023】

【Mode for Carrying out the Invention】

Preferred embodiments of the present invention will be described below in detail with reference to the accompanying drawings.

【0024】

Figs. 1-6 show an example of lancing unit and the structural parts according to the present invention. As better shown in Figs. 1 and 2, the lancing unit U in this embodiment includes a case 1, a lancet 2, a cap 29 and a sensor holder 3.

【0025】

The case 1 is a supporter made of synthetic resin, and includes a generally cylindrical tubular portion 10 having an end (upper end) formed with an opening 12,

and a bottom portion 11 connected to another end (lower end) of the tubular portion 10. The tubular portion 10 has an inner circumferential surface formed with a projection 13, which stops the rotation of the case 1 in fitting the case 1 around a part of a lancing apparatus A, which will be described later. A film 14 as a lid for closing the opening 12 is bonded to the upper surface of the case 1, whereby the case 1 is hermetically closed. As the film 14, use may be made of one made of an aluminum foil or one provided by laminating a resin film onto an aluminum foil.

【0026】

As better shown in Figs. 3, the lancet 2 includes a body 20 made of synthetic resin and a metal needle 21 held by the body 20 with its tip end protruding out of the body 20. The body 20 is so configured as to be properly mounted to a lancet holder 5 of the lancing apparatus A, which will be described later, and formed with a plurality of ribs 22 extending in the same direction as the needle 21 and with a recess 23. The recess 23 is formed when holding the needle 21 in a cavity of a mold for performing insert molding so that the needle 21 is held by the body 20. Such recess 23 may be used for attachment of the lancet 2 to the lancing apparatus A which will be described later.

【0027】

The cap 29, which is an example of needle cover according to the present invention, is formed integrally on the body 20 by resin molding for covering the needle 21 and extends on the front end side (lower end side) of the body 20 in the same direction as the needle 21. The boundary portion 28 between the cap 29 and the body 20 is constricted to be smaller in diameter than other portions, for facilitating divide of the two parts. The cap 29 has a lower end formed with a hole 29a. As shown in Fig. 6, the hole 29a can be fitted to a projection 15 projecting from the bottom portion 11 of the case 1. By the fitting, the cap 29 is held in the case 1 in a standing posture. In the present invention, conversely to the above structure, the bottom portion 11 of the case 1 may be formed with a recess, whereas the bottom of the cap 29 may be formed with a projection to be fitted in the recess. The cap 29 is bonded to the case 1 with an adhesive. Instead of using an adhesive, the bonding may be performed by ultrasonic welding or thermal fusing. This holds true for the bonding between other portions of the lancing unit. The needle 21 of the lancet 2 is subjected to sterilization by e.g. γ -ray irradiation before it is incorporated into the case 1. Preferably, in the case 1 is further disposed a desiccant (not shown) for keeping the quality of a sensor S, which will be described later.

【0028】

The sensor holder 3 is an example of analyzing member of the present invention. As better shown in Fig. 4, the sensor holder 3, which is made of synthetic resin, includes a side wall 31 having an arcuate cross section and a horizontal wall 32 connected to the side wall 31. The horizontal wall 32 has a bottom surface which is inclined, for example, and to which the sensor S is attached.

【0029】

The sensor S is in the form of a chip and has a structure as shown in Figs. 5A and 5B, for example. The sensor S includes a substrate 390 on which are provided a reagent 39a containing enzyme which undergoes certain reaction (e.g. oxidation reaction) with glucose in blood, and a pair of electrodes 39b for electrically detecting the degree of the reaction. On the substrate 390 are also provided a pair of spacers 391 spaced from each other, and a cover 392 for covering the spacers 391, all of which serve to define a capillary 393. The substrate 390, each of the spacers 391 and the cover 392 are continuously formed with a recess 394 which serves as a blood introduction port. When blood is applied to the recess 394, the blood travels through the capillary 393 by capillary action and is guided to the reagent 39a.

【0030】

As shown in Fig. 4, the horizontal wall 32 of the sensor holder 3 is formed with a pair of through-holes 32a and a pair of holding walls 32b. The paired through-holes 32a are utilized for inserting a pair of measurement probes 62 of the lancing apparatus A, which will be described later, to bring the measurement probes 62 into contact with the paired electrodes 39b of the sensor S. The paired holding walls 32b can be fitted around a lower portion 29b of the cap 29 so as to clip the lower portion from opposite sides. For example, the lower portion 29b of the cap 29 is columnar, whereas the paired holding walls 32b are curved into a generally arcuate shape corresponding to the circumferential surface of the lower portion. As shown in Figs. 1 and 2, by fitting the paired holding walls 32b around the lower portion of the cap 29, the sensor holder 3 is attached to the case 1 via the cap 29. However, the sensor holder 3 is slidable upward for detachment from the cap 29.

【0031】

Figs. 7-16 show an example of lancing apparatus suitable for using the above lancing unit U.

【0032】

As shown in Fig. 7, the lancing apparatus A of this embodiment includes a housing 4, a lancet holder 5 arranged in the housing 4, a latch member 59 and other members to be described below.

【0033】

The housing 4 is provided by connecting three sleeves 40a-40c constituting a front end portion, an intermediate portion, and a rear end portion in series and is fixed to an outer case 70. The sleeve 40a has a front end (lower end) which comes into contact with the skin of a human body in performing lancing and which has an opening 41. As shown in Fig. 11, the sleeve 40a has a configuration and a size which make it possible to fit the case 1 of the lancing unit U to the sleeve by sliding. The sleeve 40a has an outer surface formed with a groove 42 for receiving the projection 13 of the case 1. The groove 42 extends longitudinally of the sleeve 40a to prevent the rotation of the case 1 in fitting the case 1 around the sleeve 40a. In the lancing apparatus A, the lancet 2 and the sensor holder 3 of the lancing unit U are mounted to the lancing apparatus A by sliding and fitting the case 1 around the sleeve 40a, whereby the lancet 2 and the sensor holder 3 are precisely guided to predetermined positions in the lancing apparatus A, which will be described later.

【0034】

As better shown in Fig. 8, in the sleeve 40a, a holding portion 6 is provided. The holding portion 6 serves to hold the sensor holder 3 of the lancing unit U and corresponds to an example of a second holding means according to the present invention. The holding portion 6 includes an attachment 60, fixed to the inner

surface of the sleeve 40a, which is made of synthetic resin and includes a first and a second walls 60b and 60c defining a space 60a. As shown in Figs. 12 and 13, the space 60a is a portion for inserting the side wall 31 of the sensor holder 3 of the lancing unit U from below. The holding portion 6 is provided with a spring 61, and when the side wall 31 enters the space 60a, the spring 61 exerts a resilient force F for pushing the side wall 31 toward the second wall 60c, or toward the central portion of the sleeve 40a, for holding the sensor holder 3. Of course, for reliable holding of the sensor holder 3, an engaging member may be provided between the sensor holder 3 and the holding portion 6.

【0035】

As better shown in Fig. 13, the space 60a has a width s_1 which is larger than the thickness t_1 of the side wall 31 of the sensor holder 3. Therefore, when the side wall 31 of the sensor holder 3 attached to the case 1 is inserted into the space 60a, a gap 60a' is defined between the side wall 31 and the second wall 60c.

Therefore, as shown in Fig. 14, when the sensor holder 3 and the cap 29 are separated from each other, the resilient force F of the spring 61 presses the side wall 31 against a side surface of the second wall 60c.

【0036】

Referring to Figs. 7 and 8, the paired measurement probes 62 are held in the second wall 60c of the holding portion

6. The paired measurement probes 62 for coming into contact with the paired electrodes 39b of the sensor S extend axially of the housing 4. Each of the measurement probes 62 has an expandable and contractible front end 62a which is extended downward by a resilient force of an appropriate spring (not shown) when the sensor holder 3 is not mounted to the lancing apparatus A. As shown in Figs. 12-14, when the sensor holder 3 is mounted to the holding portion 6, the front end 62a is pushed upward by the sensor S for contraction. Though not shown, the paired measurement probes 62 are electrically connected to a control circuit provided in the outer case 70. The control circuit, which comprises e.g. a CPU and a memory attached thereto, performs computation of the glucose level in blood introduced to the reagent 39a based on the current detected via the paired measurement probes 62.

【0037】

The lancet holder 5 is fitted in the sleeve 40b rotatably and slidably in the axial direction. The lancet holder 5 has a lower end formed with a recess 50. By pushing the body 20 of the lancet 2 into the recess 50, the lancet 2 is removably held by the lancet holder 5. The inside of the recess 50 is formed with a plurality of grooves into which the ribs 22 of the body 20 of the lancet 2 are fitted. With such an arrangement, when the body 20 of the lancet 2 is fitted into the recess 50, the relative

rotation between the body 20 and the lancet holder 5 is prevented. As shown in Fig. 9, the lancet holder 5 has a head portion 51 having a circumferential surface formed with a plurality of equiangularly spaced projections 52. The projections 52 are fitted in and guided along a plurality of first guide grooves 43A and second guide grooves 43B formed at an inner wall surface of the sleeve 40b.

【0038】

The first guide grooves 43A serve to rotate the lancet holder 5 when the lancet holder 5 is pushed upward by the lancet 2 of the lancing unit U. The first guide grooves are inclined relative to the axial direction of the sleeve 40b. The second guide grooves 43B serve to guide the straight movement of the lancet 2 and the lancet holder 5 when these parts are caused to advance to lance the skin of a human body with the lancet 2, and extend straight in the axial direction of the sleeve 40b. Figs. 10A-10E are developed plan view of part of the first and the second guide grooves 43A and 43B, which are actually connected to each other. (In these figures, the nearby portions of the first and the second guide grooves 43A and 43B are cross hatched.) When the lancet holder 5 moves in the axial direction of the housing 4, the projections 52 move along the first and the second guide grooves 43A and 43B. The specific operation will be described later in detail.

【0039】

As shown in Figs. 7 and 8, the latch member 59 is connected to an upper portion of the lancet holder 5 and slidably accommodated in the housing 4. The latch member 59 has a lower end into which a bush 58 is non-rotatably fitted. In the bush 58, a plurality of projections 53 projecting from the upper surface of the lancet holder 5 are rotatably inserted. With such an arrangement, the lancet holder 5 is rotatable, whereas the latch member 59 does not rotate in accordance with the rotation of the lancet holder. The upper end of each of the projections 53 engages the upper end of the bush 58 so as not to drop therefrom, whereby the lancet holder 5 and the latch member 59 are connected to each other.

【0040】

The latch member 59 has an upper portion formed with a pair of latch pawls 59a. Each of the latch pawls 59a serves to engage with an edge of a respective one of paired cutouts 44 formed in the sleeve 40c. As will be described later, this engagement occurs when the lancet holder 5 and the latch member 59 are pushed upward by the lancet 2 of the lancing unit U. To the upper portion of the sleeve 40c are mounted a pusher 71 for releasing the latch, and an operation cap 72 connected to the pusher. Between the pusher 71 and an intermediate wall 59b of the latch member 59 is provided a spring 73. The spring 73 may comprise a compression coil spring, for

example. The operation cap 72 is slidable relative to the sleeve 40c in the axial direction thereof. Thus, when the operation cap 72 is pushed down while compressing the spring 73, the pusher 71 also moves downward in accordance with the movement of the operation cap to press the latch pawls 59a. As a result, as shown in Fig. 16, the latch pawls 59a are forcibly disengaged from the edges of the cutouts 44, whereby the latch member 59 and the lancet holder 5 advance downward due to the resilient force of the compressed spring 73. In the housing 4 is also provided a return spring 74 for retreating the lancet holder 5 and the latch member 59 after the advancement.

【0041】

The operation of the lancing unit U and the lancing apparatus A will be described below.

【0042】

In the lancing unit U shown in Figs. 1 and 2, the case 1 is hermetically closed by the film 14 before the use. Therefore, the reagent 39a of the sensor S is not exposed to e.g. moisture, whereby the quality deterioration in a short period of time is prevented. Since the needle 21 of the lancet 2 is covered by the cap 29 and the cap 29 is integrally formed on the body 20 of the lancet 2, the needle is also hermetically sealed. Therefore, the sterilized state of the needle can be properly

maintained from the state before the lancet 2 is incorporated into the case 1.

【0043】

The lancing unit U is manufactured by mounting the lancet 2 provided with the cap 29 into the case 1, mounting the sensor holder 3 to the cap 29, and then sealing the opening 12 of the case 1 by the film 14. Therefore, the manufacture is easy. Specifically, the manufacture of the lancing unit U is easy particularly because the lancet 2 can be mounted just by fitting the hole 29a of the cap 29 to the projection 15 of the case 1 and the sensor holder 3 can be mounted just by fitting the paired holding walls 32b around the cap 29, thereby reducing the product cost. In the lancing unit U, particular parts for supporting the lancet 2 and the sensor holder 3 within the case 1 need not be additionally provided. Therefore, the total number of parts is relatively small, and the entire structure is relatively simple, so that the lancing unit U can be manufactured at further low cost.

【0044】

To use the lancing unit U, the film 14 is broken or peeled off to expose the opening 12 of the case 1, and then the case 1 is fitted around the sleeve 40a of the lancing apparatus A, as shown in Fig. 11. By this operation, the body 20 of the lancet 2 is fitted in the recess 50 of the lancet holder 5 to be held by the lancet holder

5. As the case 1 is slid upward in the direction indicated by the arrow N1, the lancet 2 pushes the lancet holder 5 upward. As a result, the lancet holder 5 and the body 20 of the lancet 2 rotate in the direction indicated by the arrow N2, whereby the boundary portion 28 between the lancet 2 and the cap 29 is twisted and broken.

【0045】

Specifically, as shown in Fig. 10(a), the projections 52 of the lancet holder 5 are initially located within the second guide grooves 43B, and then move closer to the first guide grooves 43A, as indicated by the arrow N3 in Fig. 10(b). To cause this movement, either the front ends of the ribs 22 of the body 20 of the lancet 2 or the grooves in the recess 50 of the lancet holder 5 are inclined to be helical so that the lancet holder 5 rotates in the direction indicated by the arrow N3 through a slight angle when the body 20 is fitted into the recess 50. Subsequently, when the lancet holder 5 is pushed upward by the lancet 2, the projections 52 move along the first guide grooves 43A, as shown in Figs. 10(c) and 10(d). This operation causes the lancet holder 5 to rotate, whereby the body 20 of the lancet 2 also rotates. On the other hand, the cap 29 of the lancing unit U does not rotate because it is fixed to the case 1. Therefore, the boundary portion 28 between

the body 20 of the lancet 2 and the cap 29 is twisted, whereby the boundary portion 28 is broken.

【0046】

As shown in Fig. 12, when the case 1 is pushed upward by an appropriate amount, the latch member 59 also moves upward, whereby each of the latch pawls 59a engages with an edge of a respective one of the cutouts 44. Thus, the latch member 59 is latched. As shown in Fig. 13, when the case 1 is pushed upward, the side wall 31 of the sensor holder 3 enters the space 60a of the holding portion 6, and receives the resilient force F of the spring 61. When the sensor holder 3 is supported by the cap 29, the sensor holder keeps its posture while resisting the resilient force F , whereby the gap 60a' is kept between the second wall 60c and the side wall 31. The front end 62a of each measurement probe 62 is pushed upward by the sensor S and exerts a resistive force to the pushing, thereby being brought into contact with the relevant electrode 39b. Thus, the measurement probe 62 is reliably electrically connected to the relevant electrode 39b.

【0047】

After the pushing up of the case 1 is completed in the above-described manner, the case 1 is pulled down for detachment from the sleeve 40a, as shown in Fig. 14. Since the boundary portion 28 between the body 20 of the lancet 2 and the cap 29 has been twisted and broken

as noted above, the lancet 2 and the cap 29 readily separate from each other. By this separation, the lancet 2 is duly mounted to the lancet holder 5 with the needle 21 exposed, while the cap 29 is kept in the case 1. The sensor holder 3 separated from the cap 29 is secured to the holding portion 6. As noted above, in the lancing unit U and the lancing apparatus A, the mounting of the lancet 2 to the lancet holder 5, the latching of the latch member 59, the separation of the cap 29 from the lancet 2, and the mounting of the sensor holder 3 to the holding portion 6 can be performed just by fitting the case 1 around the sleeve 40a by sliding the case by an appropriate amount and then pulling out the case, which is convenient. Since the cap 29 is kept fixed to the case 1, these parts can be easily disposed of.

【0048】

When sensor holder 3 and the cap 29 are separated each other by pulling out the case 1 from the sleeve 40a, the side wall 31 of the sensor holder 3 is pressed against the second wall 60c by the resilient force F of the spring 61. As a result, the sensor holder 3 moves toward the center of the sleeve 40a (in the direction indicated by the arrow N4 in Fig. 14) by the amount corresponding to the dimension of the gap 60a' shown in Fig. 13. By moving the sensor holder 3 in this way, the sensor S

comes close to the lancing position of the lancet 2, which provides the following advantages.

【0049】

As shown in Fig. 15, after the lancet 2 and the sensor holder 3 are mounted to the lancing apparatus A by the above process, the front end of the sleeve 40a of the lancing apparatus A is brought into contact with the skin 99 of a human body as the object to be lanced. Subsequently, the operation cap 72 is pushed to advance the pusher 71. As a result, as shown in Fig. 16, each of the latch pawls 59a is disengaged from the edge of the relevant cutout 44, whereby the latch member 59 and the lancet holder 5 move downward by the resilient force of the spring 73 to cause the needle 21 of the lancet 2 to lance the skin 99. At this time, the body 20 of the lancet 2 partially engages the horizontal wall 32 of the lancet holder 3, whereby the needle 21 is prevented from sticking deep into the skin 99 more than necessary. As shown in Fig. 10(e), when the lancet holder 5 moves downward, the projections 52 move along the second guide grooves 43B, whereby the lancet holder 5 can move straight. As a result of the straight movement, the projections 52 can be located at a position which is similar to the initial position shown in Fig. 10(a), which enables the repeating of the above operation.

【0050】

After the needle 21 lances the skin 99, the latch member 59 and the lancet holder 5 immediately retreat by a predetermined amount due to the resilient force of the return spring 74 to pull out the needle 21 from the skin 99. Preferably, a pump or a pump mechanism is provided in the lancing apparatus A to generate a negative pressure in the sleeve 40a in lancing the skin. With such an arrangement, the negative pressure promotes the bleeding from the skin 99, so that the lancing amount of the needle 21 of the lancet 2 can be reduced, which is advantageous for reducing the damage to the skin 99.

【0051】

The blood extracted from the skin 99 is applied to the sensor S and guided to the reagent 39a of the sensor S. As described with reference to Fig. 14, the sensor holder 3 has approached the center of the sleeve 40a, i.e. located closer to the lancing position, so that the blood can be reliably applied to a predetermined portion of the sensor S.

【0052】

As means for positioning the sensor holder 3 close to the center of the sleeve 40a, it may be considered to mount the sensor holder 3 close to the center of the case 1 from the first in the state of the lancing unit U shown in Figs. 1 and 2. However, since the sensor holder 3 is supported by the cap 29 in the lancing unit U, the wall thickness of the cap 29 need be reduced for

positioning the sensor holder 3 close to the center of the case 1. When the wall thickness of the cap 29 is excessively reduced, the mechanical strength of the cap may be deteriorated. In such a case, the cap 29 may not reliably support the sensor holder 3. In this embodiment, however, such a problem can be avoided, because the sensor holder 3 moves closer to the center of the sleeve 40a when it is mounted to the lancing apparatus A.

【0053】

After the lancing operation is performed, the control circuit incorporated in the lancing apparatus A computes the glucose level in blood. In the lancing apparatus A, the computed value may be displayed at a display (not shown) such as a liquid crystal display, for example. The lancet 2 and the sensor holder 3 after use are detached from the lancing apparatus A and disposed of. Preferably, such detachment is performed by using a tool or a member which is designed to enter the sleeve 40a to engage and hold the lancet 2 and the sensor holder 3. In such a case, the user need not directly touch the lancet 2 and the sensor holder 3 after use.

【0054】

The present invention is not limited to the foregoing embodiments. Specific structure of each part of the

lancing unit and the lancing apparatus according to the present invention may be modified in various ways.

【0055】

The supporter of the lancing unit may comprise a member other than a case having a cylindrical portion. As the lancing member, use may be made of a member having a structure which is different from that of the above-described lancet. Although it is preferable that the cap for covering the needle of the lancing member is integrally formed on the body of the lancing member by resin molding as is in the foregoing embodiments, the present invention is not limited thereto. For example, the cap 29 may be formed integrally with the case 1. The cap, the supporter, and the body of the lancing member may be integral with each other. The body of the lancing member and the cap may be separated from each other just by a pulling force, instead of by twisting as a result of the relative rotation.

【0056】

The lancing unit and the lancing apparatus of the present invention are not limited to those used for measuring the glucose level in blood but may be structured for use in other kinds of measurement and analysis. The auxiliary part in the present invention may not comprise a sensor holder to which a sensor provided with a reagent is mounted. For example, the auxiliary part may comprise a sensor itself provided with e.g. a reagent,

and the sensor by itself may be supported by the supporter.

【0057】

In the lancing apparatus according to the present invention, In the lancing apparatus according to the present invention, the holder (second holding means) for holding the auxiliary part may not use a spring, but may be provided with a mechanism for engaging or clamping the auxiliary part, for example. Further, the holder (first holding means) for holding the lancing member may be provided with a mechanism for clamping the lancing member, for example. Further, instead of a coil spring, other biasing means may be utilized in the moving mechanism for advancing the first holding means.

【Brief Description of the Drawings】

【Fig. 1】 is a perspective view, partially cut away, showing an example of lancing unit according to the present invention.

【Fig. 2】 is a side sectional view of Fig. 1.

【Fig. 3】 (a) is a perspective view showing a lancet with a cap, and (b) is a sectional view thereof.

【Fig. 4】 is a perspective view showing a sensor holder.

【Fig. 5】 (a) is a perspective view showing a sensor, (b) is an exploded perspective view of the sensor.

【Fig. 6】 is an exploded view, partially in section, of the lancing unit shown in Fig. 1.

【Fig. 7】 is a sectional view showing an example of lancing apparatus according to the present invention.

【Fig. 8】 is a sectional view of the principal portion of Fig. 7.

【Fig. 9】 illustrates the lancet holder and the intermediate sleeve for guiding the holder.

【Fig. 10】 (a)-(e) illustrate the guiding of the projections of the lancet holder.

【Fig. 11】 is a sectional view of a principal portion in the process of mounting the lancet and the sensor holder of the lancing unit.

【Fig. 12】 is a sectional view showing the process of mounting the lancet and the sensor holder of the lancing unit.

【Fig. 13】 is a sectional view showing a principal portion of Fig. 12.

【Fig. 14】 is a sectional view showing a principal portion after the lancet and the sensor holder of the lancing unit are mounted to the lancing apparatus.

【Fig. 15】 is a sectional view showing an example of use of the lancing apparatus.

【Fig. 16】 is a sectional view showing an example of use of the lancing apparatus.

【Fig. 17】 (a) is a sectional view showing a prior art lancing unit, whereas (b) is a sectional view showing a prior art lancing apparatus.

【Legend】

U lancing unit
A lancing apparatus
S sensor
1 case (supporting member)
2 lancet (lancing member)
3 sensor holder
4 housing
5 lancet holder
6 holding portion
10 cylindrical portion
12 opening (of the case)
14 film (lid)
20 body (of the lancet)
21 needle (of the lancet)
28 boundary portion
29 cap (needle cover)

【Identification of the Document】 ABSTRACT

【Abstract】

【Object】

To provide a usable lancing unit capable of preventing increasing the size of the lancing apparatus.

【Means】

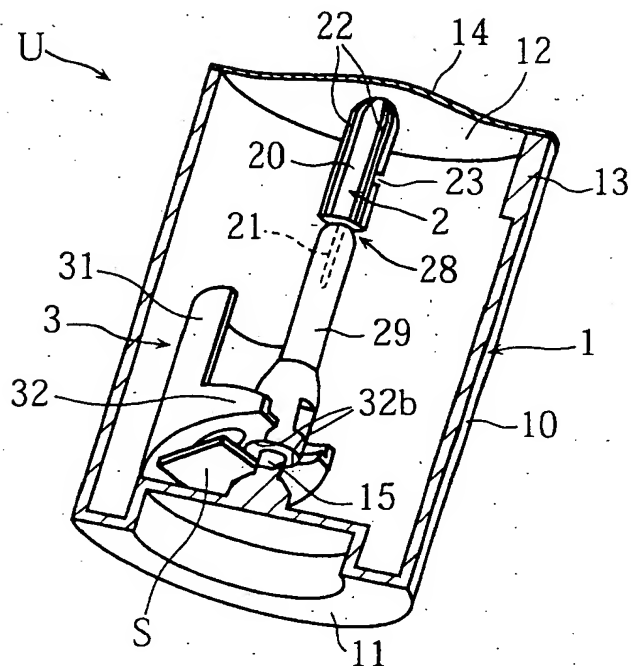
A lancing unit U includes a lancing member 2, an auxiliary part 3, and a supporter 1 supporting each of the lancing member and the auxiliary part. The lancing member 2 and the auxiliary part 3 are detachably supported by the supporter 1. Preferably, the lancing unit further includes a cap 29 for covering a needle 21 of the lancing member 2, detachable from the lancing member 2. The cap 29 is attached to the supporter 1 or integrally formed on the supporter 1, so that the lancing member 2 is supported by the supporter via the cap 29.

【Selected Figure】 Fig. 1

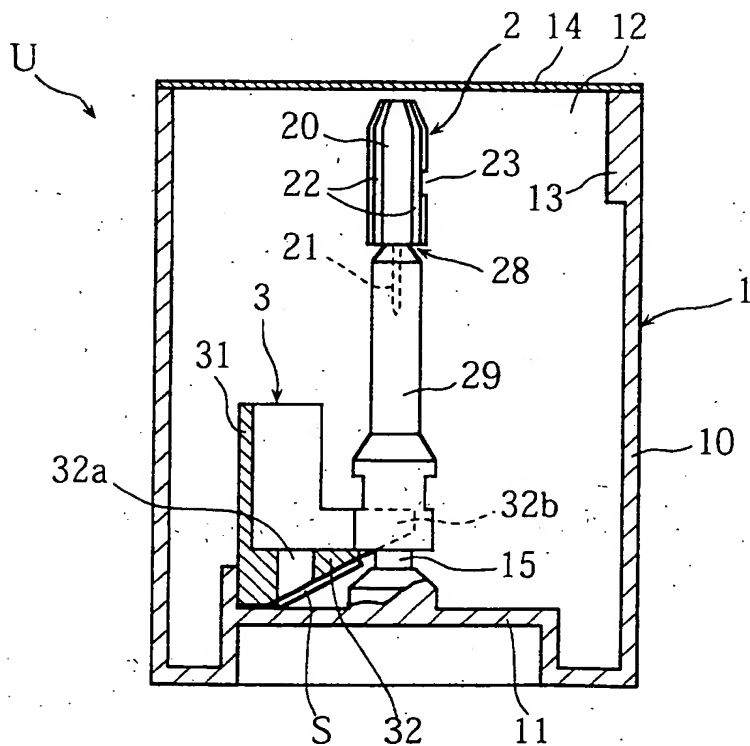
【Identification of Document】

Drawings

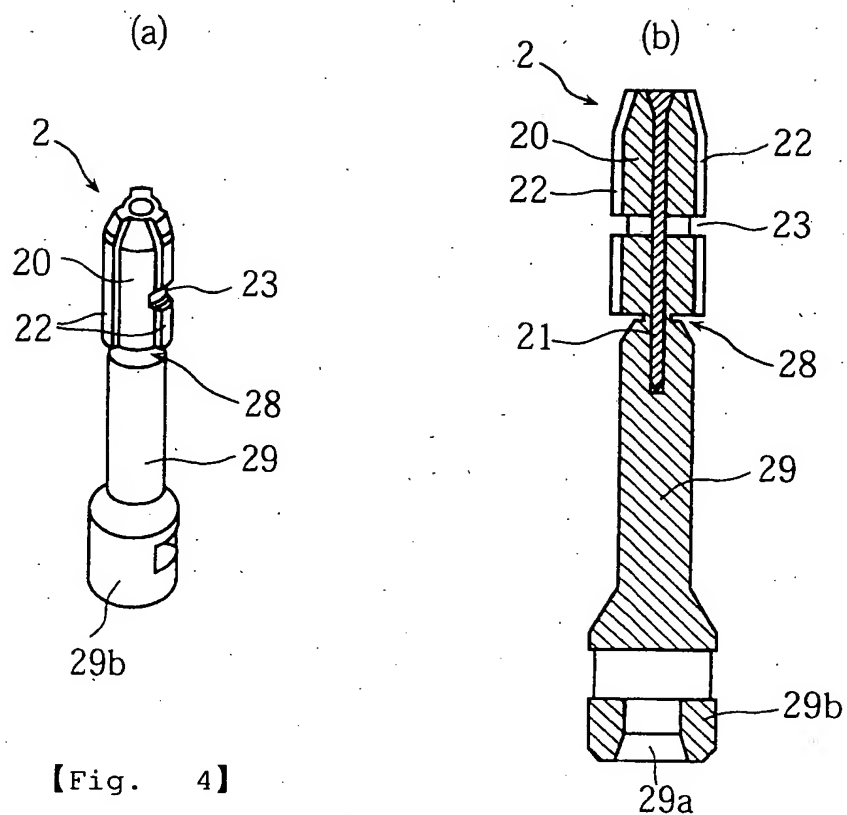
【Fig. 1】



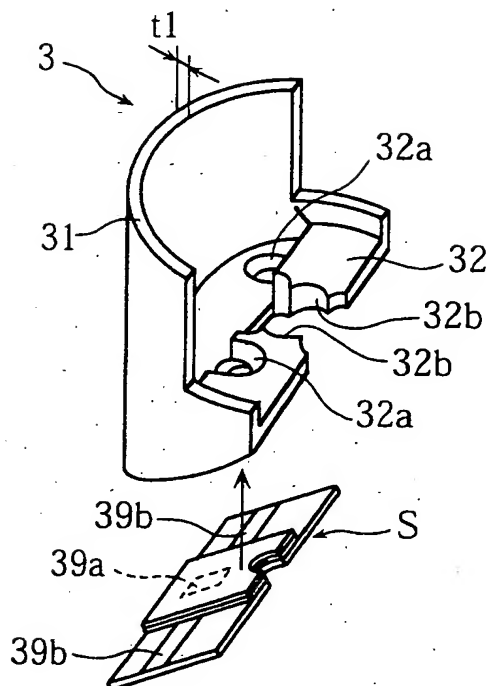
【Fig. 2】



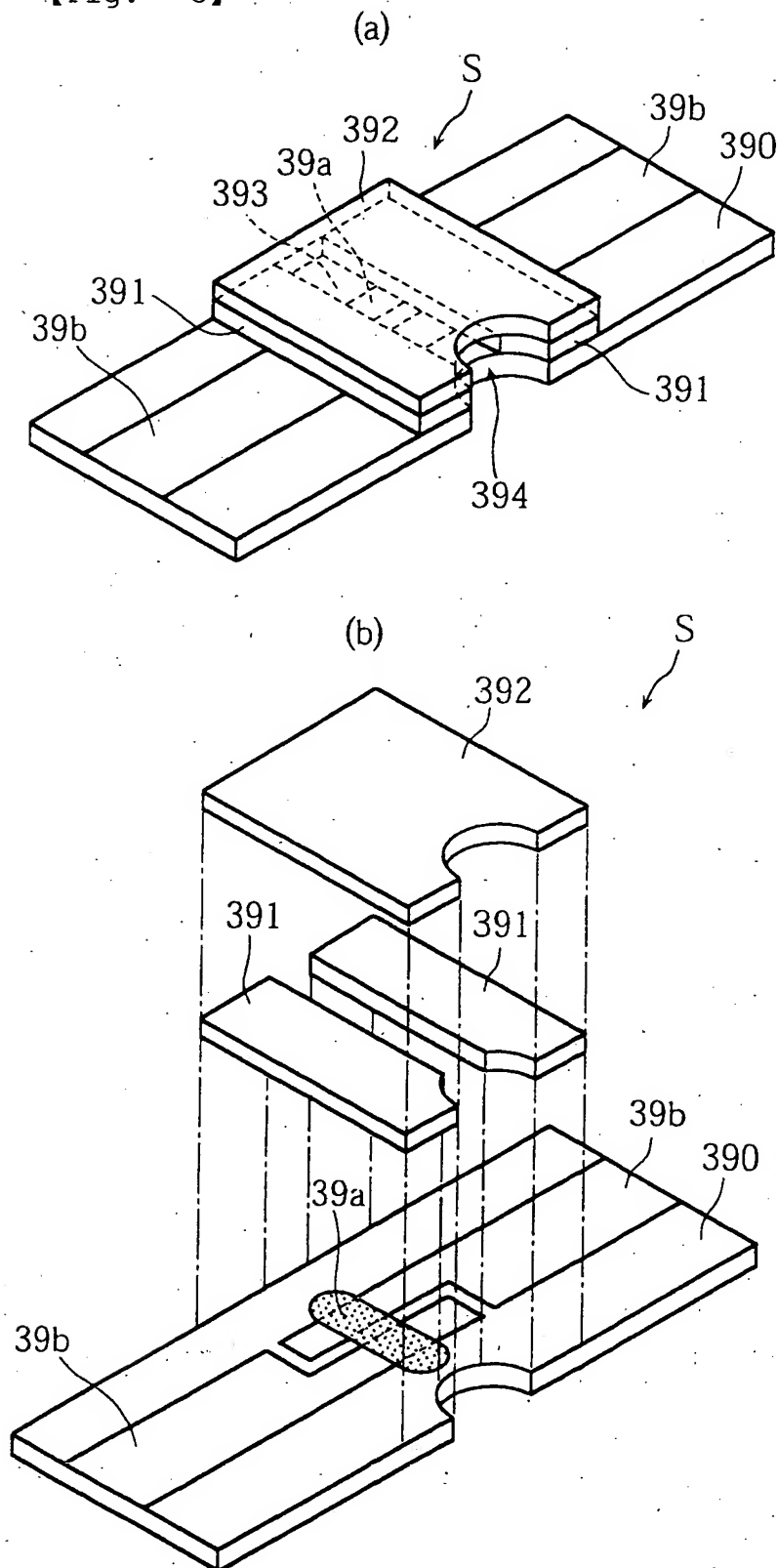
【Fig. 3】



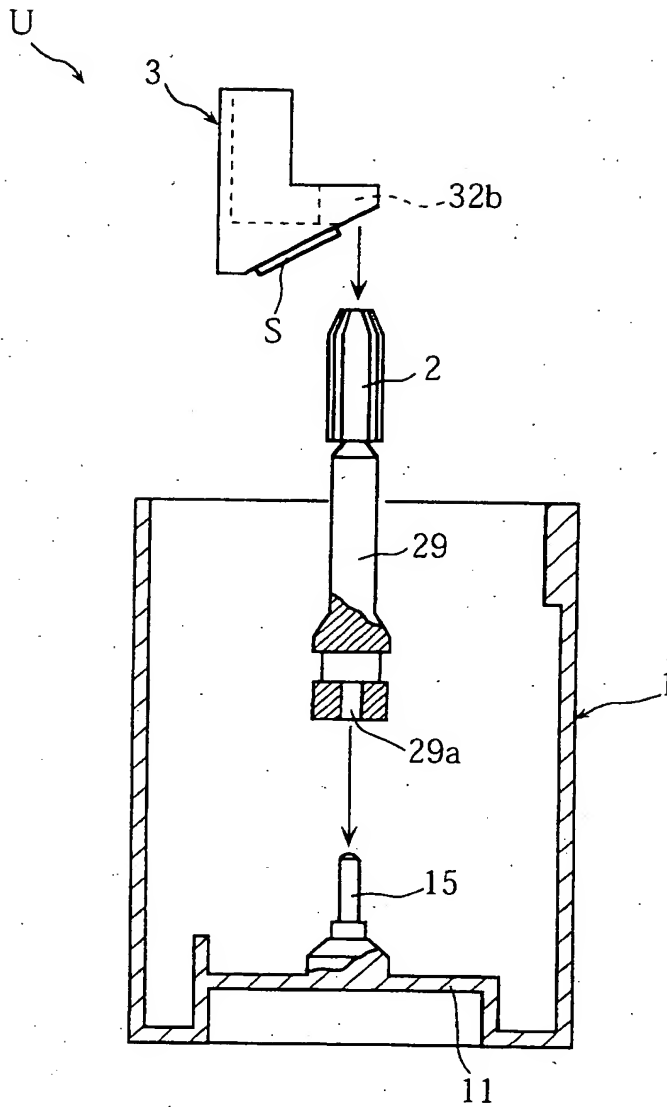
【Fig. 4】



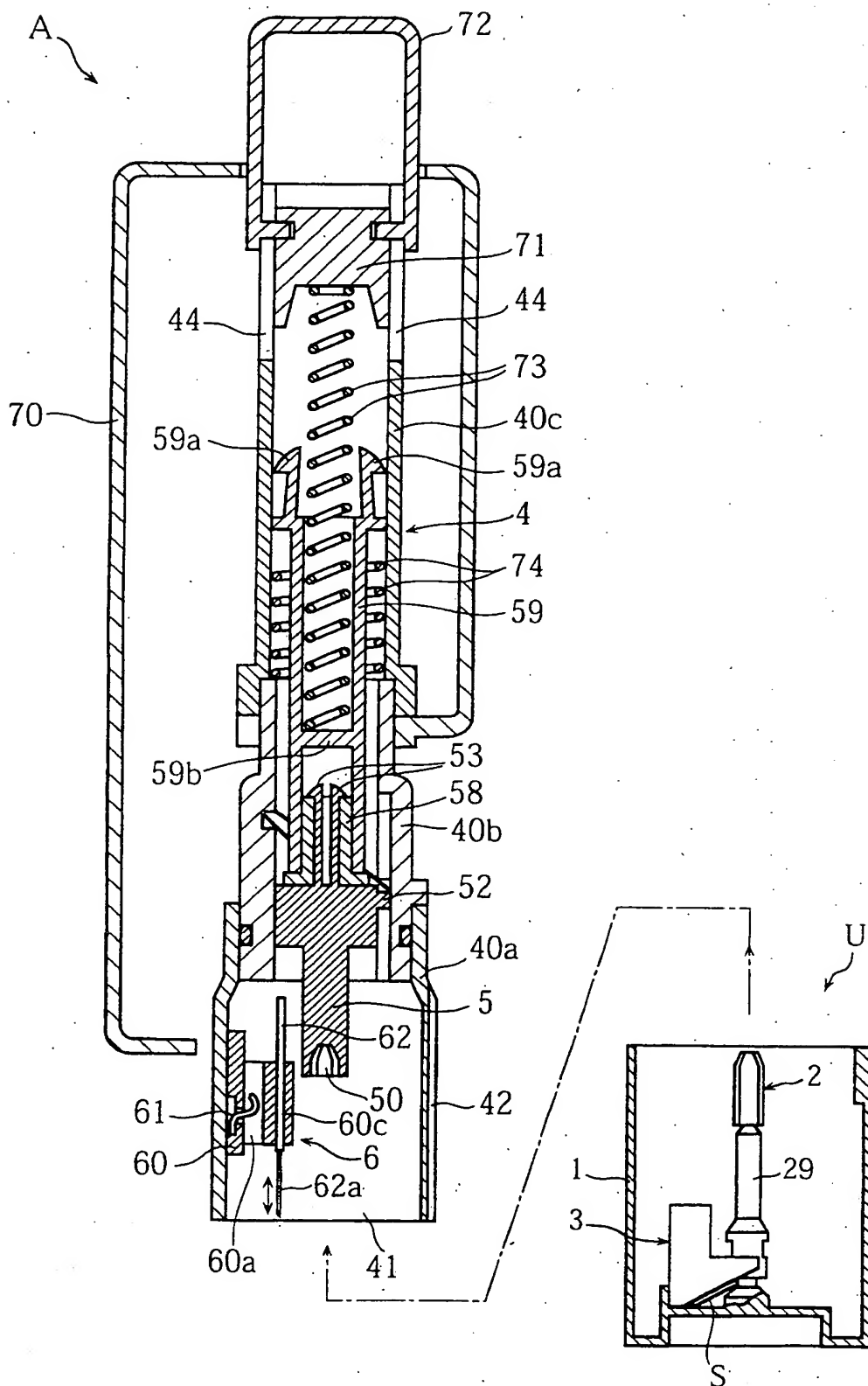
【Fig. 5】



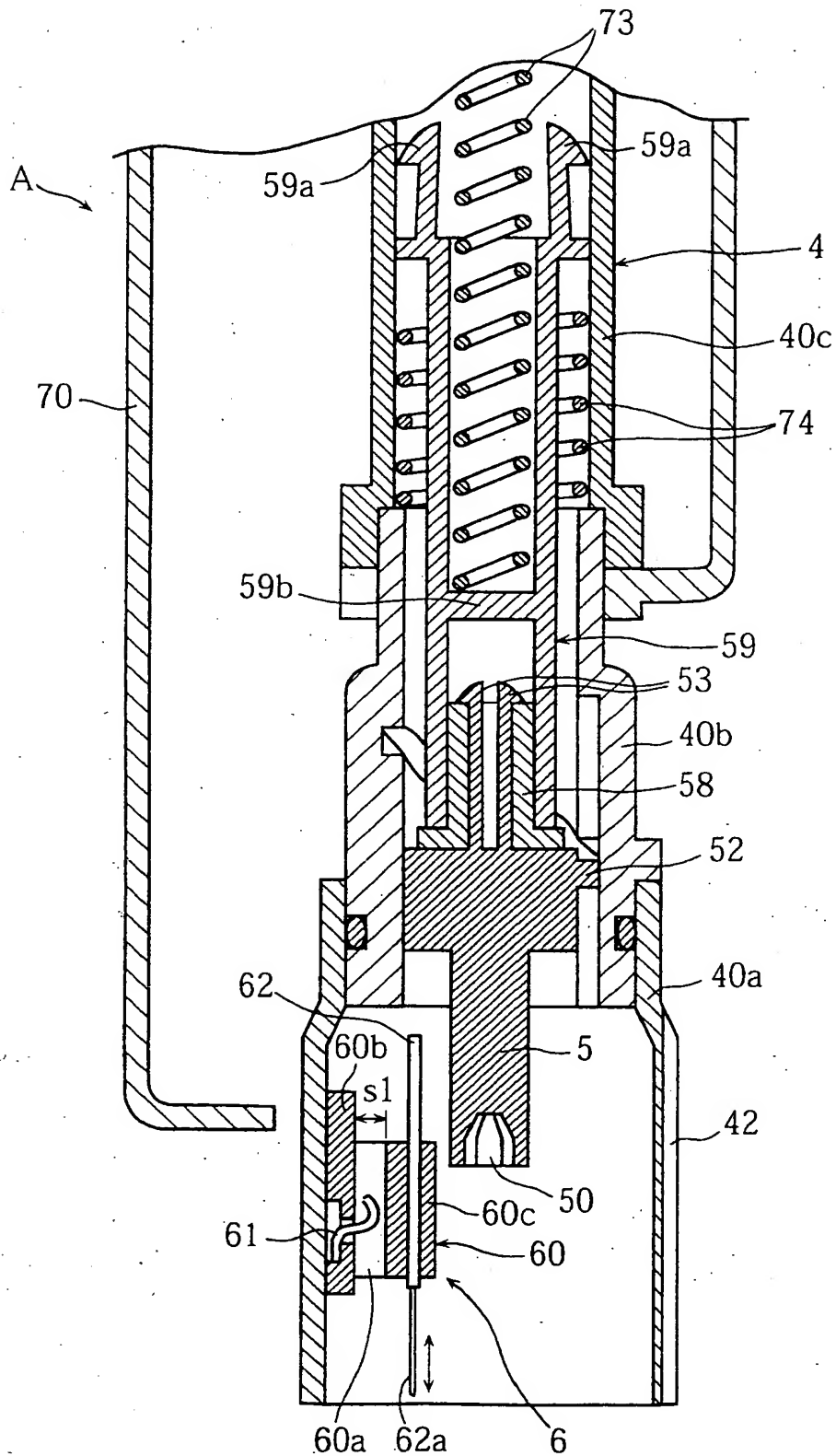
【Fig. 6】



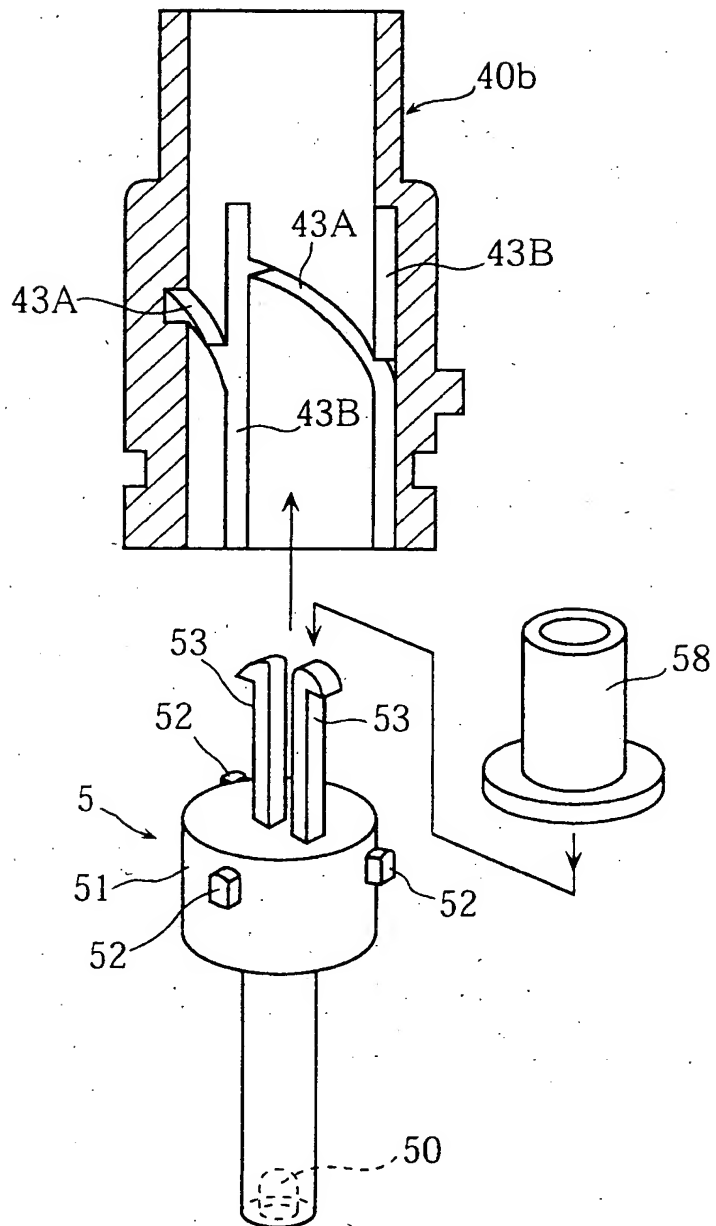
【Fig. 7】



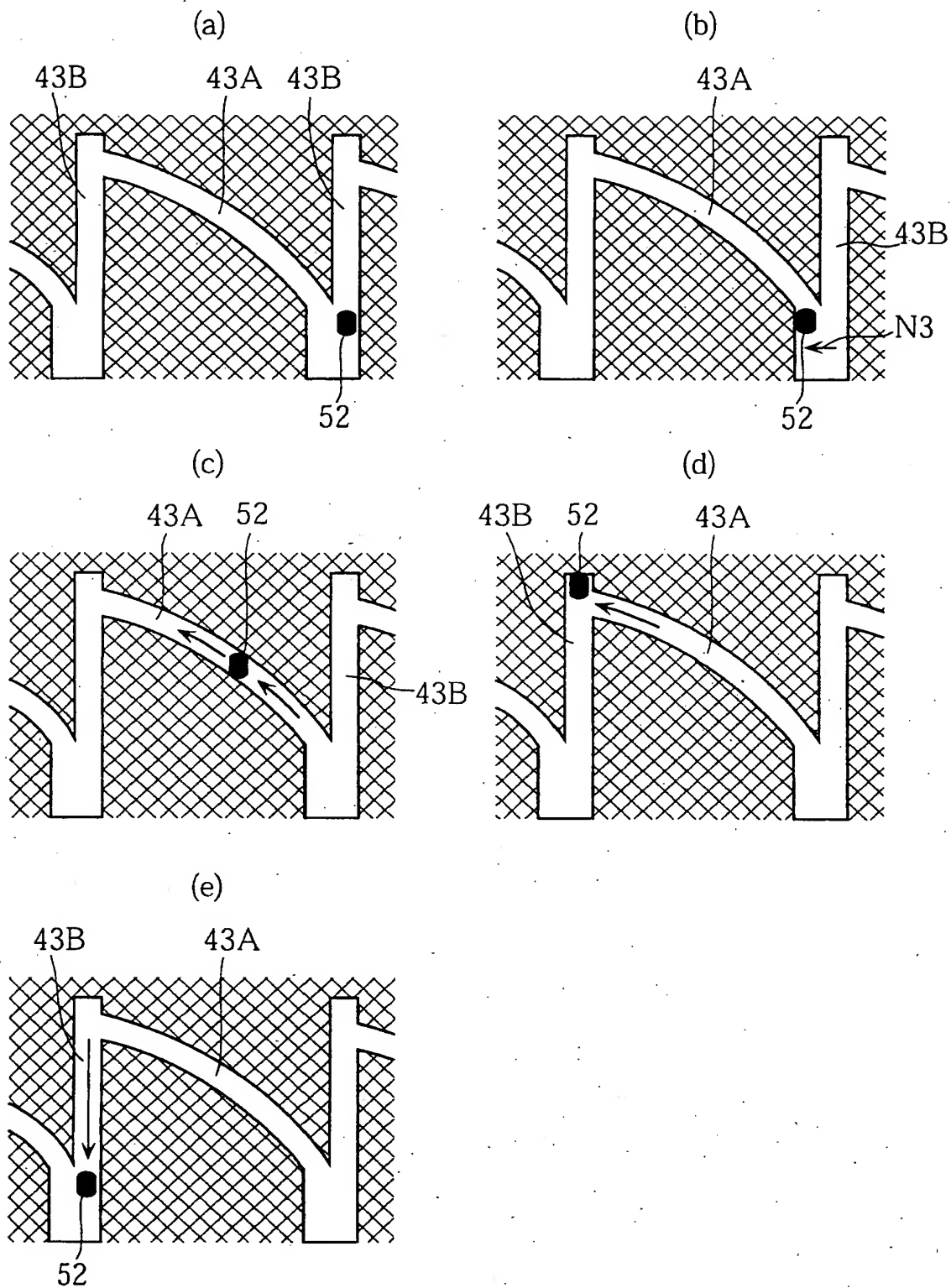
【Fig. 8】



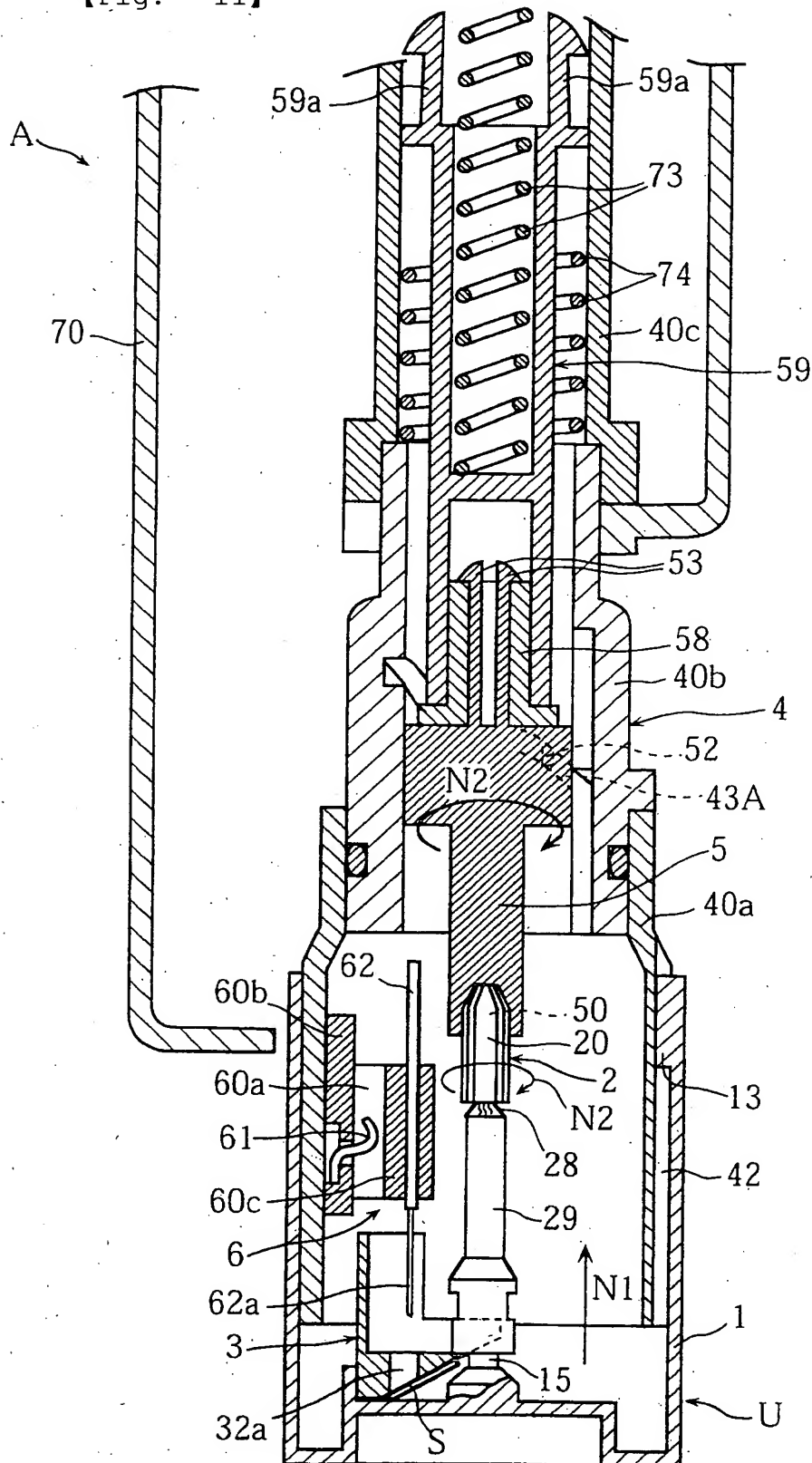
【Fig. 9】



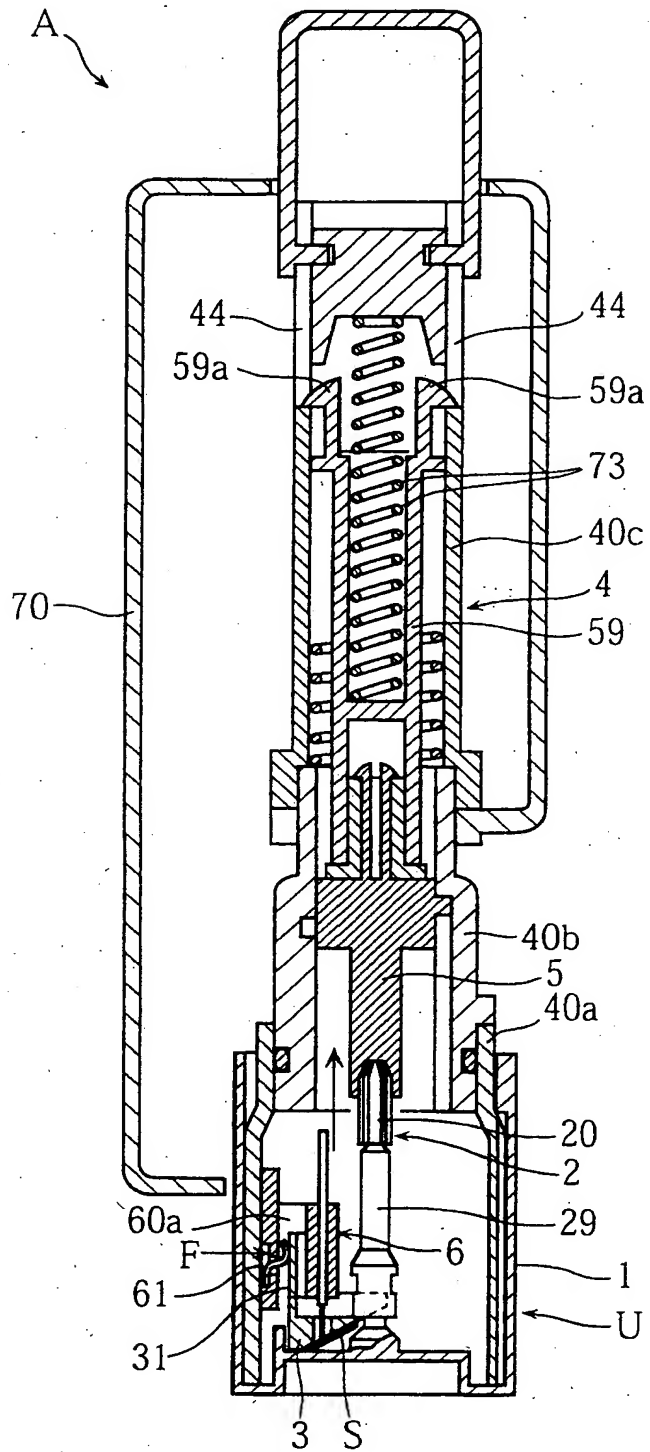
【Fig. 10】



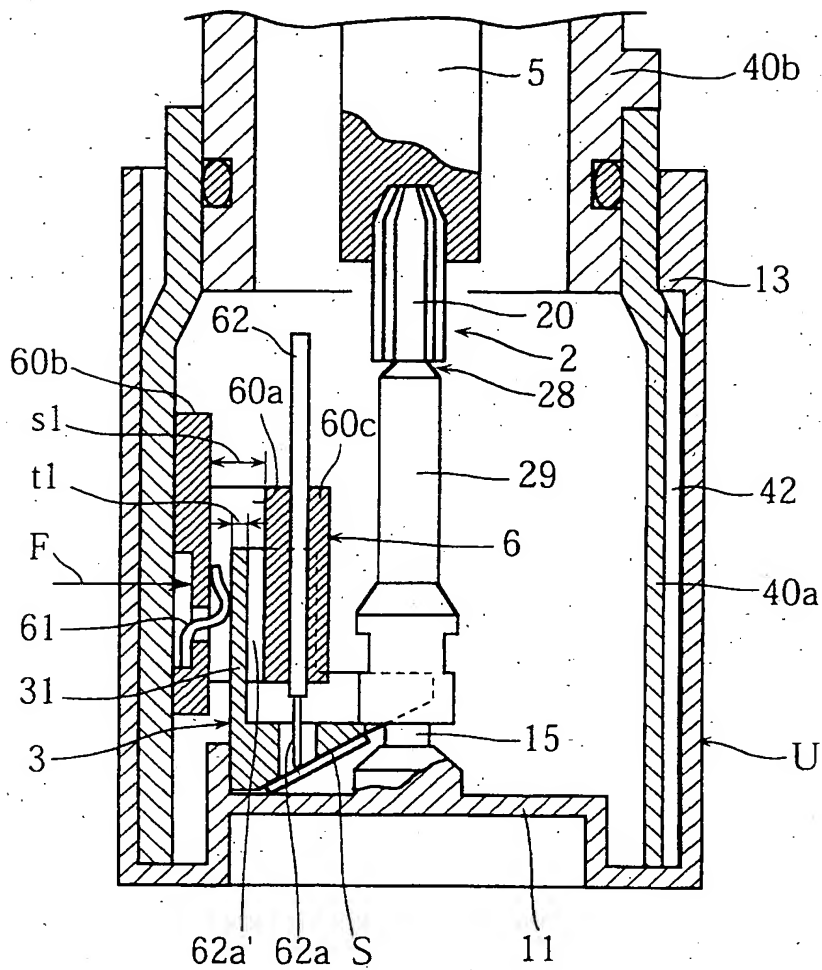
【Fig. 11】



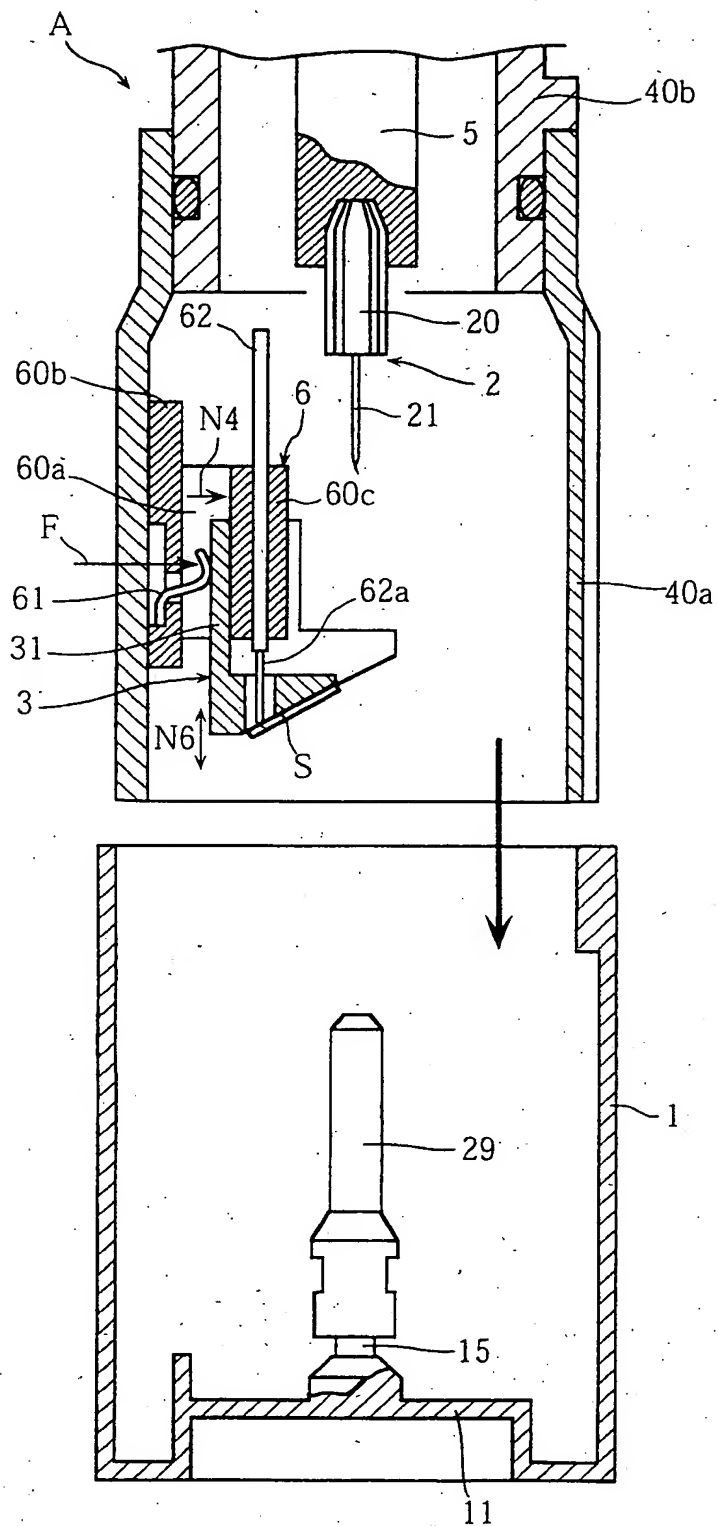
【Fig. 12】



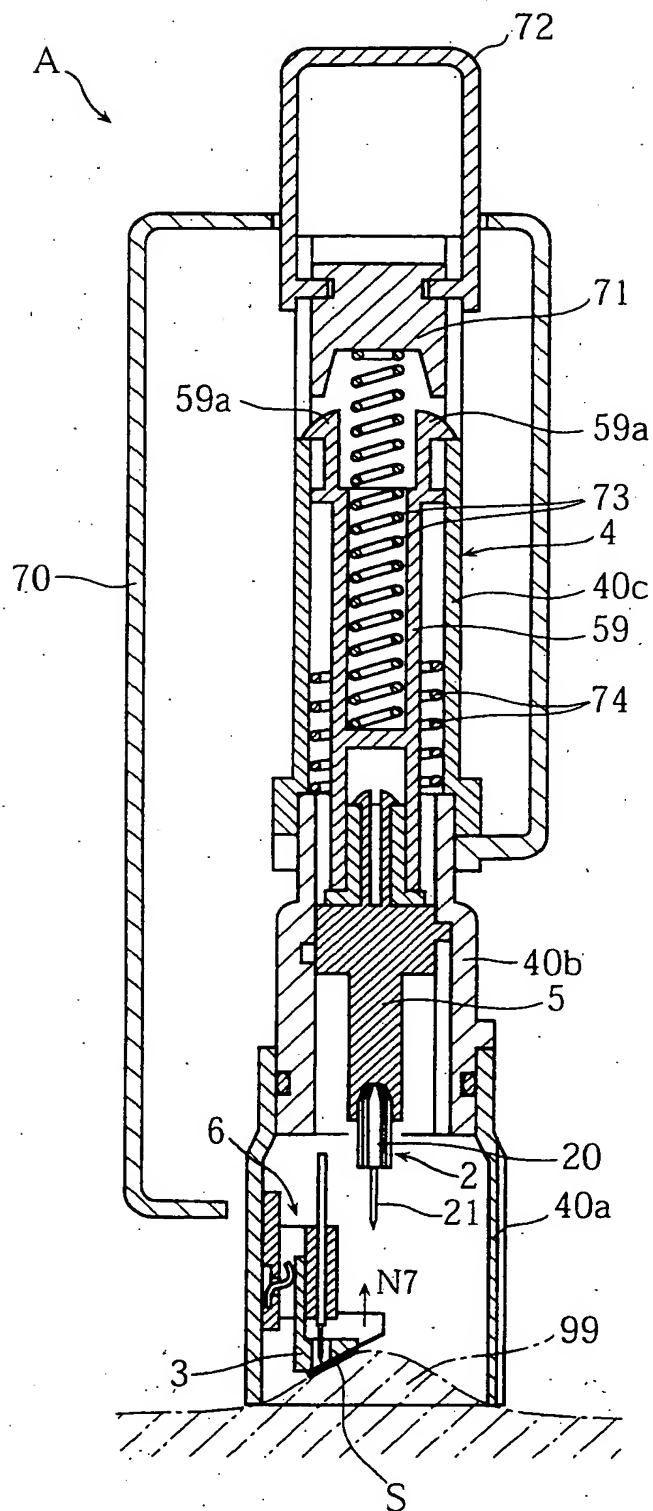
【Fig. 13】



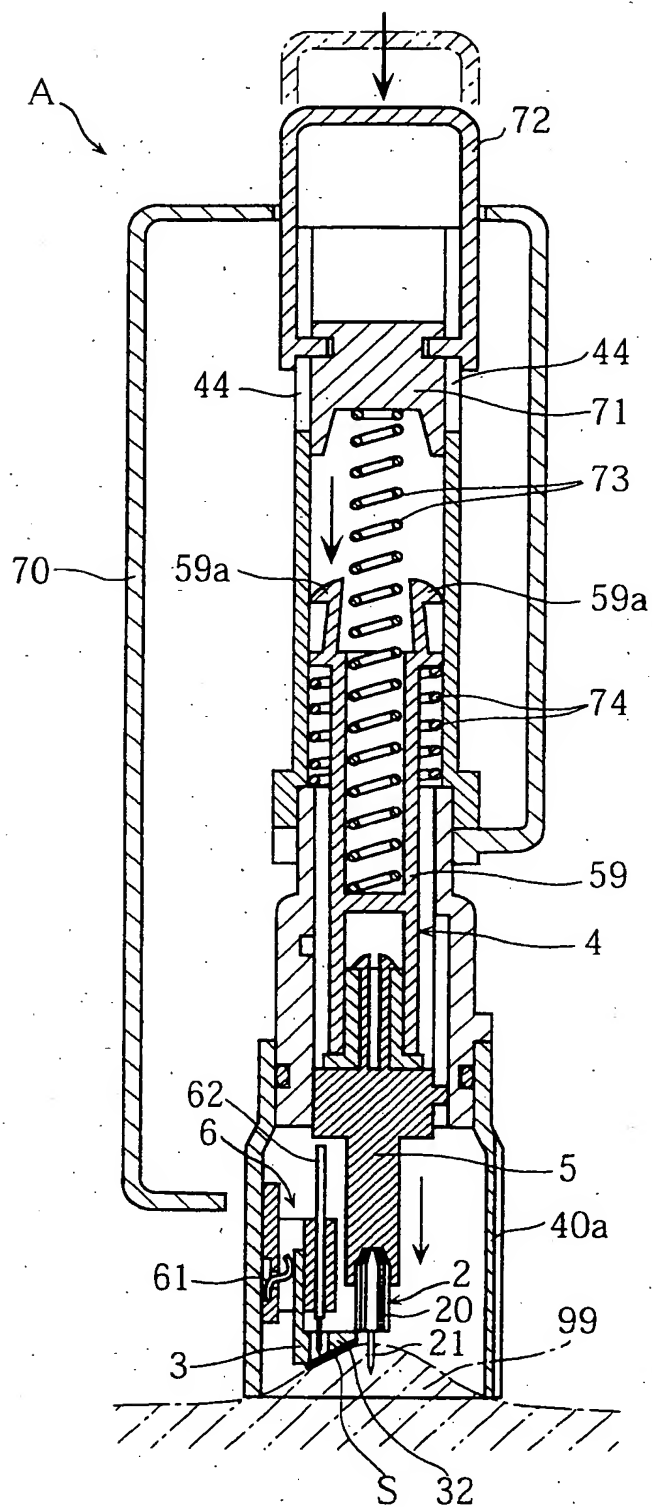
【Fig. 14】



【Fig. 15】



【Fig. 16】



【Fig. 17】

